FDA Alert for Healthcare Professionals

Nimodipine Capsules
(marketed as Nimotop)

FDA ALERT [01/2006): The FDA has requested that Bayer add a boxed warning to the nimodipine (Nimotop) labeling to warn about medication administration errors with nimodipine. Nimodipine is approved for oral administration to improve neurological outcome after subarachnoid hemorrhage. When administered intravenously or parenterally, it can cause serious adverse events, including death. Nimodipine must not be administered intravenously or by any parenteral route.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available..

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program and complete a form on line at http://www.fda.gov/medwatch/report/hcp.htm or report by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided on line, or by telephone to 1-800-FDA-1088.

Recommendations

Healthcare providers who prescribe, dispense or administer Nimodipine should

- Administer nimodipine capsules orally only.
- For patients unable to swallow a capsule, use an oral syringe to extract the gel inside the capsule. The syringe should be labeled "for oral use only". The nimodipine gel should be administered through the patient's naso-gastric tube or G-tube, followed by 30 ml normal saline solution (0.9%).
- Ensure that nimodipine is never administered intravenously, or by any parenteral route.

Data Summary

- The FDA has received reports of medication administration errors in which nimodipine was given intravenously or parenterally, rather than orally.
- In addition to a fatal case reported in 2005, there has been a history of these errors. Two cases were reported in 1995. Another case, which resulted in death, was reported in 1996. Additional non-fatal cases were reported in 1999, and in 2002 (two cases).
- After the 1996 case, the manufacturer, Bayer, included a bolded statement in the labeling, warning against incorrect administration.
- Because cases are still occurring, FDA has asked Bayer to add a boxed warning to the nimodipine labeling to describe the life-threatening risk of parenteral administration.

Report serious adverse events to
FDA's MedWatch reporting system by completing a form on line at
http://www.fda.gov/medwatch/report/hcp.htm,
by faxing (1-800-FDA-0178),
by mail using the postage-paid address form provided on line
(HF-2, 5600 Fishers Lane, Rockville, MD 20853-9787),
or by telephone (1-800-FDA-1088).
Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@cder.fda.gov

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Additionally, FDA has requested that Bayer develop an oral solution of nimodipine for use in patients who cannot swallow a capsule.

- Nimodipine is a calcium-channel blocker, which lowers blood pressure; when the drug is administered intravenously instead of orally, the effect can be much stronger, leading to cardiovascular collapse and possibly to death.

Nimotop Labeling (approved 1/20/2006)